K003458

MAY - 3 2001

Section 6.0 510(k) Summary

Submitter: Clinical Innovations, Inc.
Name: Wm. Dean Wallace
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Proprietary Names: Soft Beat Fetal Heart Rate Electrodes
Common/Usual Name: Fetal Scalp Electrode
Classification Name: Fetal Scalp Circular Electrode and applicator

The legally marketed devices to which equivalence is claimed are: Life Trace Fetal Spiral Electrode (K943732), Corometrics Spiral Electrode (K792669), HP Spiral Scalp Electrode (K771553), Medi-Trace Fetal Monitoring Spiral Electrode (K904745), MAI Fetal Scalp Electrode (K872057), Surgicraft Copeland Disposable (K844608).

Description of the device: The Soft Beat Fetal Scalp Electrode consists of a soft vacuum cup in which a Ag/AgCl electrode is attached. A tube from the cup is connected to a bellows which is hand activated to 1) develop a level of vacuum such that the cup is firmly attached to the fetal scalp and 2) to maintain a lower vacuum level to maintain the attachment of the cup to the scalp. A connector with recessed sockets connects the main electrode and the reference electrode to a reusable cable which in turn is connected to the fetal monitor.

Intended use: For patients requiring fetal heart rate monitoring during labor.

The Soft Beat Fetal Heart Rate Electrodes are substantially equivalent to the predicate devices because: they have the same intended uses, namely, use for monitoring fetal heart rate, and they have the same basic technological characteristics as predicate devices, namely, an electrode that attaches to the fetal scalp. They use the same or similar materials, all of which have been shown to be biocompatible and to function well in the intended application.

The safety and effectiveness are similar to existing devices as demonstrated in the laboratory and in clinical testing. Biocompatibility testing shows that the materials used in the Soft Beat Fetal Heart Rate Electrodes are safe for this application. Effectiveness is the same as the predicate devices. The laboratory testing verified the performance.

Wm. Dean Wallace — Nov. 6, 2000

Wm. Dean Wallace, M.D., Ph.D. — Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

William Dean Wallace, M.D., Ph.D.
President
Clinical Innovations, Inc.
6477 S. Cottonwood Street
MURRAY UT 84107

Re: K003458
Soft Beat Fetal Scalp Electrode SBT-7000
Dated: February 27, 2001
Received: March 1, 2001
Regulatory Class: II
21 CFR §884.2675/Procode: 85 HGP

Dear Dr. Wallace:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K003458

11.0 Indications For Use

Device Name: Soft Beat Fetal Heart Rate Electrode

510(k) Number:

Indications for use: For patients requiring fetal heart rate monitoring during labor.

(PLEASE NO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003458